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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,140	01/03/2005	Michael Brines	KW00-2B02-US	7619

20583 7590 05/28/2008

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EXAMINER
WOODWARD, CHERIE MICHELLE

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
05/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Interview Summary	Application No.	Applicant(s)	
	10/520,140	BRINES ET AL.	
	Examiner	Art Unit	
	CHERIE M. WOODWARD	1647	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Cherie Woodward*.

(2) *Laura Coruzzi*.

(3)*Anthony Cerami, Inventor*.

(4)*Sebastian Martinek*.

Date of Interview: *21 May 2008*.

Type: a)☐ Telephonic b)☒ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☒ Yes e)☐ No.
If Yes, brief description: *MS PowerPoint presentation showing the differences between natural EPO and the claimed genus of EPO structural derivatives binding to the EPOR homodimer and the EPOR-beta heterodimeric receptors. The presenation demostrated that the structural changes in the claimed genus of EPO derivatives would reduce or inhibit binding to the EPOR homodimer, thus reducing the level of erythropoietic activity, because binding to the EPOR homodimer is required for induction of hematopoiesis and erythropoietic activity. However, the claimed genus of EPO strucutral derivaties were unable to bind with and activate the EPOR homodimer, but were still able to bind to the EPOR-beta heterodimer and function in a tissue protective manner. Applicant demonstrated that the strucuture-function relationship of the claimed genus of EPO structural derivatives would permit binding to EPOR-beta, activaing tissue protection, but not trigger erythropoietic activity because of the reduced ability of the claimed genus of EPO derivatives to bind to the EPOR homodimer.*.

Claim(s) discussed: *All pending and under examination*.

Identification of prior art discussed: *Art cited in 35 USC 112, first paragraph rejection*.

Agreement with respect to the claims f)☐ was reached. g)☒ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *See Continuation Sheet*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/Cherie M. Woodward/
Examiner, Art Unit 1647
Examiner's signature, if required

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

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The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Amendments to claim 8 were proposed by bringing the structural limitations of claim 11 into independent claim 8. The genus of tissue protective cytokines was also proposed to focus on EPO and specifically on the structural EPO derivatives. Applicant's PowerPoint presentation clarified the structure-function relationship and compared natural EPO binding to both the EPOR homodimer and the EPOR-beta heterodimer, with the binding of exemplary members of the claimed genus of EPO structural derivatives, such as CEPO. The applicant referred the examiner to Examples 4, 6, and 7 of the specification and page 29, paragraph 91, for data that was shown in the MS PowerPoint presentation. The examiner raised concerns with the lack of guidance and questions of possession, regarding the structural variants set forth in claim 11 and suggested that the claim subparts could be clarified to state which amino acid residues or domains are capable of being mutated, substituted, deleted, or otherwise modified, and permit the derivative EPO to maintain function, especially insofar as it binds EPOR-beta, but not EPOR. Concern was raised about a lack of antecedent basis in the dependent claims, should claim 8 be amended to recite EPO having the recited modifications of claim 11. The dependent claims will need to be amended to reflect the specificity of the recited EPO derivatives instead of the generic tissue protective cytokines. Applicant's representative stated that amendment to the claims would be forthcoming. The examiner also noted that the next Office Action would likely contain obviousness type double patenting rejections in light of the proposed instant claim amendments, amendments made to previously filed claims in copending applications, and the presence of new recently filed applications.

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